PUK11

COST-MINIMIZATION ANALYSIS: MIRCERA (METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA) VS. ARANESP (DARBEPOETIN ALFA) IN PATIENTS WITH CHRONIC KIDNEY DISEASE (CKD) WHO ARE NOT RECEIVING HAEMODIALYSIS, IN POLISH SETTING

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OBJECTIVES: To assess and compare costs and effects of Mircera vs. Aranesp treatment of pre-dialysis patients. **METHODS:** A systematic review of medical data bases according to EBM principles was conducted. Efficacy and safety data for both treatment options were compared. No significant differences in clinical efficacy and safety of both treatments were identified. Cost-minimization analysis was conducted in order to compare costs. The analysis was performed from the perspective of public payer in a two-year time horizon. Only direct cost data, gathered in three reference centers in Poland, were taken into account (drug's costs, drug administration and adverse events costs). According to Polish HTA Agency guidelines costs were discounted by 5%. Dosing schemes for both drugs were assumed based on the assumptions of the National Health Fund Therapeutic Area Program for the CKD patients in pre-dialysis period: Mircera- 50 µg s.c.(mean monthly dose), Aranesp: 10 µg once weekly, or 20 µg—once per 2 weeks or 40 µg once monthly i.v. or s.c (mean dosing was calculated). Sensitivity analysis was done to test the robustness of the results. Results were tested for changes in the value of accounting points defined by the payer (+/–20%), discounting rate for costs and changes in drug dosing. **RESULTS:** CMA showed savings of 1 194 PLN (1 EUR = 4.55 PLN) per patient with Mircera treatment vs. Aranesp in the 2 year horizon. Savings were due to the once monthly Mircera administration scheme. Results of the basic analysis were confirmed by the sensitivity analysis. **CONCLUSIONS:** Mircera treatment of CKD patients in pre-dialysis period is as effective and safe as Aranesp therapy, but offers savings to the public payer.

PUK12

COST-EFFECTIVENESS OF ACE INHIBITOR THERAPY TO PREVENT DIALYSIS IN NON-DIABETIC NEPHROPATHY—INFLUENCE OF THE ACE INSERTION / DELETION POLYMORPHISM

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OBJECTIVES: End Stage Renal Disease (ESRD) is associated with high health care costs and low quality of life (QoL) compared to Chronic Kidney Disease (CKD). The renoprotective effectiveness of ACE inhibitors (ACEi) is largely determined by the ACE insertion deletion (I/D) polymorphism. We determined the cost-effectiveness of ACEi therapy in non-diabetic nephropathy for the ACE II/ID and for the ACE DD genotype. Furthermore, we considered a selective screen-and-treat strategy where patients are prescribed alternative therapy based on their ACE (I/D) polymorphism. **METHODS:** Time-dependent Markov models were constructed; cohorts of 1000 patients were followed for 10 years. Data were mainly gathered from the Ramipril Efficacy In Nephropathy (REIN) trial. Both univariate and probabilistic sensitivity analyses were performed. **RESULTS:** ACEi therapy compared to placebo both reduces costs and improves QALY's more in the ACE DD group (€105,104 and 0.553 QALYs gained per patient) than in the ACE II/ID group (€15,826 and 0.091 QALYs gained). Sensitivity analyses demonstrated a 30.2% probability of ACEi therapy being not cost-effective in the ACE II/ID group, against an almost 100% probability of cost-effectiveness in the ACE DD group. Cost of dialysis had the largest influence on the cost-effectiveness. An alternative treatment for patients with the ACE II/ID genotype, incorporated in a selective screen-and-treat strategy, should feature a 9.1% increase in survival time for the strategy to be cost-effective. High alternative treatment effectiveness and dialysis costs improve the cost-effectiveness of a screening strategy. **CONCLUSIONS:** ACEi therapy is a cost saving treatment in non diabetic nephropathy, irrespectively of ACE (I/D) genotype. However, ACEi therapy saved more costs and more health gaines were achieved in the ACE DD genotype than in the ACE II/ID genotype. An alternative treatment featuring a modest increase in survival time for patients with the ACE II/ID genotype can be incorporated in a cost-effective screen-and-treat strategy.

URINARY/KIDNEY DISORDERS – Patient-Reported Outcomes Studies

PUK13

DEVELOPMENT AND VALIDATION OF A QUESTIONNAIRE (SIGIT-QOL) TO EVALUATE THE EFFECTS OF GASTROINTESTINAL SYMPTOMS ON HEALTH RELATED-QUALITY OF LIFE IN SOLID-ORGAN TRANSPLANT RECIPIENTS WITH A FUNCTIONING GRAFT

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OBJECTIVES: To develop and validate a brief questionnaire to evaluate the effects of gastrointestinal (GI) symptoms on HRQoL in solid-organ transplant recipients. **METHODS:** Two phases study: 1)Development of pilot version of questionnaire (SIGIT-QOL): bibliography review, list of areas and items included in the questionnaire, panels of 8 experts and 50 patients and questionnaire modification to reach consensus and final version, and 2)Questionnaire validation: multicenter (34 centers) observational 6 weeks study in solid-organ transplant recipients (kidney, liver, heart and lung) 3 to 12 weeks post-transplantation. Patients responded to the new questionnaire and to the GastroIntestinal Quality of Life Index-GIQLI; age, sex, transplant date, acute rejection and GI symptoms evaluated by physicians were registered. Psychometric properties of SIGIT-QOL questionnaire (feasibility, content, construct and convergent validity and reliability) were evaluated. **RESULTS:** The first phase generated a questionnaire of 17 items. 274 patients participated in second phase: mean age 52.7(7.59)years, 66.3%males. Mean time from transplant 6.7(3.1) months, 44(16.4%) patients presented acute rejection and 44.4% GI symptoms. 95.5% patients responded to all items of SIGIT-QOL in 6.37(5.6) minutes vs 12.12(11.83) minutes of GIQLI. According to factorial analysis, all items were grouped in one dimension with a reliability (Cronbach's alpha) of 0.88. Mean score was 57.80(9.8) (theoretical range: 0–68). A moderate, positive significant correlation with GIQLI (r = 0.67), and a mild negative correlation with physician's evaluation of GI symptoms, were found. **CONCLUSIONS:** A new 17-items questionnaire SIGIT-QOL has been developed; it shows good feasibility, validity and reliability to evaluate the effects of gastrointestinal symptoms on health related-QoL in solid-organ transplant recipients with a functioning graft.

PUK14

HOW DO PATIENTS DESCRIBE THEIR SYMPTOMS OF INTERSTITIAL CYSTITIS/PAINFUL BLADDER SYNDROME (IC/PBS)? QUALITATIVE INTERVIEWS WITH PATIENTS TO SUPPORT THE DEVELOPMENT OF A PATIENT-REPORTED SYMPTOM-BASED SCREENER FOR IC/PBS

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OBJECTIVES: The National Institutes of Diabetes and Digestive and Kidney Diseases (NIDDK) requires cystoscopic features of interstitial cystitis (IC) as a diagnostic criterion, yet this excludes significant numbers of patients with clinical symptoms of IC/Painful Bladder Syndrome (PBS). Patient-reported, symptom-based measures may be more appropriate for identifying IC/PBS patients. Existing measures have poor specificity, likely due to inadequate content validity. The objective was to conduct qualitative interviews with patients to identify key IC symptoms, and the language used to describe them, to develop a new symptom-based IC screener. **METHODS:** A total of 44 IC/PBS patients with a confirmed diagnosis in the US, France and Germany (aged 22–72) were interviewed about their symptoms and subsequent impact on quality of life. Ten US overactive bladder (OAB) patients (aged 31–69), a condition often confused with IC, were also interviewed to improve specificity. Interviews included open-ended questions, creative tasks and focussed discussion. Thematic analysis was conducted utilising grounded theory methods. **RESULTS:** Key symptoms identified by IC/PBS patients were the urge to urinate, urination frequency, and pain. Urge had four components: 1) need to urinate driven by pain; 2) a need to urinate to avoid pain getting worse; 3) a constant need to urinate and; 4) a sudden need to urinate. In contrast, OAB patients reported urge that did not involve pain. Both OAB and IC/PBS patients experienced high day and night-time urination frequency. IC pain was perceived to be in the bladder, abdomen or pelvis, and was most commonly described as "pressure", "burning", "sharp" and "discomfort". The screener items were developed using these data, with guidance from IC experts. **CONCLUSIONS:** Utilising an extensive, geographically diverse interview process, we elicited key symptoms that differentiate IC/PBS from OAB patients. Efforts to optimize the sensitivity and specificity of the new screener are critical to accurately identify patients with IC/PBS.

PUK15

STRESS URINARY INCONTINENCE: ASSESSMENT OF WOMEN'S PREFERENCES

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OBJECTIVES: A French epidemiological study found that 19% of women aged 18–70 years could be classified as having stress urinary incontinence (SUI). Our study explores SUI women's willingness to seek medical treatment and their preferences relative to different therapeutic options. **METHODS:** A telephone survey was conducted among 1000 women aged 18–70 with SUI. Women willing to be treated were asked about their preferences between perineo-sphincter exercises, TVT surgery and an oral medication. A simple conjoint analysis was conducted in order to explore the structure of preferences between surgery and medication conditional to the probability of success and the out-of-the-pocket cost of therapies. Preferences about exercises were not assessed any further since the results of a pilot study indicated that most women would tend to try this therapy before any of the others. **RESULTS:** Fifty-five percent of the women are willing to try medication or surgery in the next six months. 92% of these women gave consistent answers in the conjoint analysis exercise. They are more concerned with the nature of the treatment (importance weight of 40%) than with having to pay €45 to try it (importance weight of 29%). According to this analysis, it is predicted that 71% of these women would prefer a surgery with 95% chance of success and reimbursed to a medication with 60% chance of success and costing €45 the trial. However, when asked directly about their preferences, the estimations